UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

ESPERION THERAPEUTICS, INC., Plaintiff, -against- DAIICHI SANKYO EUROPE GMBH, Defendant.	No. 1:23-cv-02568-ER **DEFENDANT DAIICHI SANKYO EUROPE GMBH'S PROPOSED DISCOVERY PLAN FOLLOWING THE PARTIES' RULE 26(F) CONFERENCE**

Pursuant to Federal Rule of Civil Procedure 26(f)(3), defendant Daiichi Sankyo Europe GmbH ("DSE") submits this proposed discovery plan.

I. INTRODUCTION

A. Explanation for Separate Submissions

Counsel for the parties conferred on Friday, June 2, 2023 about the topics listed in Rule 26(f)(2) and later communicated via email regarding the same topics and the contents of a proposed discovery plan. The parties had agreed to submit a joint report to the Court today. In preparation for a joint submission, the parties exchanged drafts yesterday, laying out their respective positions on the various topics. The draft report from plaintiff Esperion Therapeutics ("Esperion") did not comport with Rule 26(f)(3) and contained several pages of argument on the merits, including attacks on DSE and its counsel. For example, the first section of the report was titled "Subjects on Which Discovery Might Be Needed." DSE's draft for this section included one neutral sentence and then listed 8 subjects in bullet form. Esperion's draft for this section included five (5) pages of argument that either copied verbatim or closely tracked statements from its First Amended Complaints and wrongfully accused DSE of intentional bad acts without any factual basis. Indeed,

Esperion's approach to the Rule 26(f)(3) report turned on its head Local Rule 26.4's requirement that the parties "cooperate with each other" and "be courteous in their dealings" on discovery matters and scheduling.

Upon receipt of Esperion's draft, DSE (through counsel) expressed concern to Esperion. DSE requested that Esperion send a revised draft that aligned with the scope and purpose of Rule 26(f)(3) and noted that, if Esperion refused, the parties should submit separate reports. Esperion refused to provide DSE a new draft, prompting DSE to submit its own report (with a short rebuttal on the merits). DSE acknowledges that this should have been a joint report focused on the components of the discovery plan and devoid of any argument on the merits. However, DSE did not feel comfortable letting Esperion's unfounded allegations go unchallenged in the Rule 26(f)(3) report. A printout of the email exchange among counsel is attached as Exhibits 1A and 1B.

B. Responsive Statement on the Merits

Esperion's First Amended Complaint (and the draft Rule 26(f)(3) report it shared with DSE yesterday) do not reflect reality. Nor do they accurately reflect the parties' negotiations, the License and Collaboration Agreement at issue (the "Agreement"), or the deal that the parties struck regarding the results of Esperion's CLEAR Outcome Study. This is not surprising, as no one on Esperion's current management team negotiated or signed the Agreement. As explained in its Answer, DSE will demonstrate that the parties always intended the regulatory milestone payment at issue to require, among other things, that the CLEAR Outcome Study demonstrate at least a 15% relative risk reduction for its **primary** MACE-4 composite endpoint. This is the only endpoint that could on its own lead to an approved label and it is the only rational interpretation of the disputed provision here.

Esperion's allegations of "delay, delay, delay" also fall flat. DSE is not seeking (and has never sought) to delay this proceeding in any way. It simply is requesting a schedule that affords DSE a full and fair opportunity to defend itself against Esperion's claims and demonstrate to this Court why Esperion is not entitled to the declaratory relief it seeks. If delay was DSE's goal, it has not acted in furtherance of the goal. DSE (located in Germany) accepted service of process and did not insist on formal service through an international treaty or other burdensome means. DSE also answered the operative complaint instead of filing a Rule 12 motion. DSE agreed to confer about Rule 26(f) issues on June 2 (well before its counsel appeared in the case and DSE answered the complaint on June 20) and also agreed to exchange initial disclosures next week. DSE further agreed to serve written responses and objections to Esperion's First Set of Production Requests on July 7, after Esperion initially insisted that DSE serve objections on July 3 (the day before the 4th of July holiday) before begrudgingly agreeing to a 4-day extension. DSE has done its part to move the case forward but cannot agree to Esperion's unreasonable schedule.

Esperion also ignores its own conduct that caused delay. For example, Esperion chose to change lead counsel a month after filing the litigation and then filed a 37-page First Amended Complaint ("FAC") that delayed the proceeding for approximately a month. DSE had no role in these events. And rather than attempt to work with DSE on a mutually agreeable schedule, Esperion has refused to engage on the parties' initial proposals (opting for a "their way or the highway" approach) and also rejected DSE's request to peel back the rhetoric from their Rule 26(f) report, all amounting to further delay, inefficiencies and now separate reports to the Court. Moreover, if any party embodied delay during the parties' collaboration, it is Esperion. Even though the Agreement required Esperion to share all study data with DSE "promptly," Esperion waited approximately three-and-a-half months to produce the data to DSE, despite repeated

requests from DSE. Esperion also tried to lure DSE into admitting it owed the Regulatory Milestone Payment ***before*** Esperion provided DSE the data sufficient to determine the risk reduction percentages for the primary endpoint. This is not the conduct of an innocent victim.

Esperion likewise overstates the commercial impact of the CLEAR Outcome Study. While DSE remains committed to commercializing the product in Europe and promoting the positive results of the study, the results did not trigger the contingent Regulatory Milestone Payment nor did they create the commercial value on which the milestone payment was premised. DSE highlighted at least one media report that described the study results as "lacklustre" [1] and also noted how the market reacted following Esperion's disclosure of the "full" study results at the ACC conference in early March – a 37.2% decline over a several day period and before any mention of the dispute with DSE. In sum, DSE did not agree to pay Esperion $200 or $300 million for a 15-20% risk reduction of a secondary endpoint and no rational pharmaceutical company would have given the other products on the market.

DSE briefly outlines below a reasonable scope and timeline for discovery.

II. RULE 26(F) TOPICS

A. Subjects on Which Discovery Might Be Needed.

At this early stage of the case, DSE believes discovery will or may be needed on the following subjects:

1. Esperion's efforts to search for a commercial partner in Europe, including without limitation any internal or external communications, presentations, analyses, or similar documents;

[1] Madeline Armstrong, *ACC 2023 – Esperion's Outcomes Win Looks Lacklustre*, Evaluate Vantage (March 4, 2023), https://www.evaluate.com/vantage/articles/events/conferences/acc-2023-esperions-outcomes-win-looks-lacklustre#:~:text=A%2013%25%20reduction%20in%20the,its%20cholesterol%2Dlowering%20pill%20Nexletol.

2. The negotiations that led to the Agreement, including without limitation any internal and external communications, presentations, analyses, or similar documents;
3. The negotiation and drafting of the Agreement, including any internal and external communications;
4. The parties' understanding of the contingent Regulatory Milestone Payment and the commercial value it was intended to capture;
5. Any internal or external communications during the CLEAR Outcome Study related to the contingent Regulatory Milestone Payment;
6. The CLEAR Outcome Study, including without limitation its design, protocols, statistical analyses plans, study results and tables, and any internal and external communications regarding the study;
7. Esperion's disclosure of the CLEAR Outcome Study results to DSE; and
8. Any allegation, topic or claim raised in Esperion's First Amended Complaint.

DSE reserves the right to seek discovery on additional topics and to object to any topics listed in Esperion's Rule 26(f)(3) report.

B. Electronically Stored Information.

DSE anticipates the need for electronic discovery and has taken steps to ensure the preservation of relevant documents and electronically stored information. The parties will confer in good faith to develop a mutually agreeable plan or protocol regarding the discovery of electronically stored information.

C. Proposed Case Schedule

Event	DSE's Proposed Deadline
Initial Disclosures	June 30, 2023
Initial Pre-Trial Conference (subject to the Court's calendar)	July 2023
Substantial Completion of Document Production	December 1, 2023
Completion of Fact Witness Deposition and All Fact Discovery	February 9, 2024
Initial Expert Reports	March 22, 2024
Rebuttal Expert Reports	April 26, 2024
Completion of Expert Depositions and All Expert Discovery	May 22, 2024
Motion for Summary Judgment Deadline	June 28, 2024
Trial (subject to the Court's calendar)	October 2024

DSE's proposed schedule is reasonable based on the complexity of the case, the amount in dispute, and the anticipated scope and location of discovery, among other reasons.

First, the case arises from a complex License and Collaboration Agreement. The parties dispute whether a contingent Regulatory Milestone Payment set forth in the Agreement is due, and, specifically, whether a large, complex pharmaceutical clinical trial yielded data sufficient to trigger the risk reduction component of the contingent Regulatory Milestone Payment. The study at issue included a detailed clinical trial protocol that was revised multiple times before and after the Agreement was executed. It also requires an understanding of clinical trial "endpoints," the differences between "primary" and "secondary" endpoints, and what the composite "MACE-4"

endpoint means and how it differs from "MACE-3" and other secondary endpoints, among other clinical trial issues.

Given these complexities, DSE anticipates, at this early stage, approximately 12-15 fact witness depositions and multiple experts per side. Esperion's characterization of the case as "simple" is thus wrong and undermined by its own 37-page FAC, the array of topics and allegations contained in the document, the complexity of Esperion's alternative requests for relief, and the breadth of its initial Requests for Production covering a five-year time period and multiple broad categories.

Second, the amount of the contingent milestone payment sought by Esperion, $300 million, is substantial. Because the issues are complex and the stakes are high, the parties should not have to race through discovery on an unreasonable timeline. DSE's proposed schedule is already accelerated and far from delayed – approximately 7 months to complete all fact discovery and just over 10 months to complete all discovery (fact and expert). This is well within the bounds of reasonableness for a case of this magnitude and complexity.

Third, DSE is located in Germany. Most if not all of the relevant custodians subject to document collection reside outside of the United States. Given DSE's location, discovery of information and data in Europe will implicate the European Union's General Data Protection Regulation ("GDPR") and other related data privacy issues. According to the European Union, GDPR "is the toughest privacy and security law in the world." [2] DSE is subject to GDPR and also European "works councils," which can require layers of approval before documents can be collected and processed. In addition, some documents may require translation into English. While DSE is prepared to move efficiently through the process, Esperion's proposed case schedule does

[2] GDPR.eu, *What is GDPR, the EU's new data protection law?* at https://gdpr.eu/what-is-gdpr/.

not provide anywhere near enough time for DSE to address the necessary processes and issues raised by a cross-border dispute of this magnitude.

Esperion's proposed case schedule rests on misleading assertions and inapposite caselaw (if Esperion cites the same cases that appeared in its draft Rule 26(f)(3) report). The first, *Beacon Constr. Co., Inc. v. Matco Elec. Co., Inc*., 521 F.2d 392, 399 (2d Cir. 1975), was a simple contract dispute with an award of $3,516, which, even accounting for inflation, is far less than the hundreds of millions at stake here. The second, *Chachkes v. David*, 2021 WL 101130, at *6 (S.D.N.Y. Jan. 12, 2021), settled before any case management plan was submitted or status conference was held. Contrary to Esperion's representations, this is not a simple case and counting the number of counts or claims does not make it any less so. Esperion "single" count for declaratory judgment requests three (3) different declarations (some of which are pled in the alternative) that cover multiple contractual clauses. Dkt. 19 at p. 36. The First Amended Complaint is also far from simple and covers a broad range of topics over a five-year time period. As evident from DSE's Answer and Affirmative Defenses, Dkt. 33, many of these topics are disputed and DSE is entitled to discovery into them.

As a few examples, Esperion includes allegations concerning the negotiations between the parties, Dkt. 19, ¶¶ 29-42; whether Esperion received interest from any other potential partners, *id.* ¶ 29; the drafting history of the contract at issue, *id.* ¶¶ 35-42; whether the results of the CLEAR Outcome Study were "spectacular," as Esperion claims, *id.* ¶ 6; how and when Esperion shared with DSE the results of the CLEAR Outcome Study, *id.* ¶¶ 62-64; the reaction to study results made public by Esperion, *id.* ¶¶ 65-68; and the baseless suggestion that DSE intentionally repudiated the contract, *id.* ¶¶ 80-84. Esperion is not allowed to smear DSE with a litany of

allegations in a 37-page filing and then handcuff DSE's ability to defend against those allegations by imposing an unreasonably short schedule.

Esperion's proposed schedule is simply unworkable for this case. For example, Esperion has proposed August 18, 2023 for the substantial completion of all document productions. That is 56 days from today. DSE filed its Answer and Affirmative Defenses three days ago on June 20. The parties have not had a Rule 16 conference or otherwise appeared before the Court. It is unrealistic to think the parties can substantially complete their respective document productions in less than 60 days in a case of this magnitude and complexity. In addition, given that several Esperion employees involved in the transaction have left the company, DSE anticipates significant third party discovery. Because of the substantial number of witnesses, the scope of Esperion's discovery requests, the likelihood that the parties will need to meet and confer about the scope of each other's requests, and other issues that naturally arise in a cross-border dispute, DSE's proposed schedule (while still ambitious) is realistic and far more reasonable.

Finally, Esperion has not provided DSE any meaningful explanation or need for its accelerated schedule. Indeed, Esperion seems more focused on playing to the media and market analysts stockholders than meaningfully engaging with DSE to devise a workable schedule for both parties. There is no valid reason the dispute needs to be resolved before a decision from the European Medicines Agency (the European analog to the FDA in the United States) on the upcoming submission based on the CLEAR Outcome Study. Esperion's claims will be adjudicated in due course, and Esperion has failed to show how a resolution in October 2024 (DSE's proposed month for trial, subject to the Court's calendar), as opposed to six months earlier, would prejudice Esperion. This is especially true when the median time in this District from the filing of a

complaint to trial in a civil suit is 47.8 months.[3] DSE has proposed a trial date nearly 30 months *earlier* than the median trial date.

D. Claims of Privilege or Protection.

Subject to modification by the parties, all claims of privilege or protection as trial materials, and the production of any information subject to such claims, will be governed by Fed. R. Civ. P. 26 and this Court's Local Civil Rule 26.2. The parties will negotiate a proposed protective order addressing these issues to present to the Court for review and approval.

E. Changes to Limitations on Discovery.

(a) Interrogatories

DSE proposes to follow Fed. R. Civ. P. 33 in all respects. The parties must coordinate efforts and avoid serving duplicative or unduly burdensome interrogatories. Also, Local Civil Rule 33.3 should be followed. It was adopted for good reason and Esperion has not presented sufficient justification to deviate from this default procedure.

(b) Rule 34 Document Requests

Consistent with Fed. R. Civ. P. 34, there shall be no limits on the number of requests to produce the parties may serve with each side reserving all of its objections. No rights, obligations, or objections available under the Federal Rules of Civil Procedure are modified by this paragraph.

(c) Requests for Admission

Consistent with Fed. R. Civ. P. 36, there shall be no limits on the number of requests for admissions the parties may serve with each side reserving all of its objections. No rights,

[3] *See* U.S. District Courts, Federal Court Management Statistics, Comparisons Within Circuit, During the 12-Month Period Ending March 31, 2023 at https://www.uscourts.gov/statistics/table/na/federal-court-management-statistics/2023/03/31-3.

obligations, or objections available under the Federal Rules of Civil Procedure are modified by this paragraph.

(d) Depositions

Each party may take up to fifteen (15) fact witness depositions, including third parties, of no more than seven (7) hours each. As the ligation progresses, and to the extent either party seeks to depose any witness remotely, the parties will confer and present to the Court for approval a protocol to govern remote depositions. Each party may take one (1) Rule 30(b)(6) deposition of no more than seven (7) hours, regardless of the number of designees identified to testify. The parties shall work together to schedule all depositions (fact and expert) at a mutually agreeable date, time and place.

(e) Third-Party Subpoenas

Absent good cause, third-party subpoenas must be served no less than 60 days prior to the deadline for completion of fact discovery. Absent good cause, the parties must exchange all third-party productions within three (3) business days of receipt of the productions or at least five (5) business before any deposition of the producing third party, whichever is earlier.

(f) Expert Discovery

The parties shall be entitled to one deposition of each disclosed expert following the deadline for the service of any rebuttal expert reports.

DSE reserves the right to seek additional discovery beyond the above limits for good cause shown, and each side reserves its rights to oppose any such requests. Attached as Exhibit 2 is DSE's proposed case management plan.

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CERTIFICATE OF SERVICE

I hereby certify that on June 23, 2023, I caused the foregoing Defendant Daiichi Sankyo Europe GmbH's Proposed Discovery Plan Following the Parties' Rule 26(f) Conference to be filed with the Clerk of the Court and served upon all counsel of record via the Court's CM/ECF system.

/s/ Toni-Ann Citera
Toni-Ann Citera